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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER
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ART UNIT	PAPER NUMBER
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*12*

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

<b>Office Action Summary</b>	<b>Application No.</b> 09/326,244	<b>Applicant(s)</b> HOCHMAN, DARYL W.	
	<b>Examiner</b> Marjorie Moran	<b>Art Unit</b> 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on 11 January 2001.
- 2a) ☐ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 2-11 and 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 2-11 and 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- |                                                                                                              |                                                                              |
|--------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 15) <input type="checkbox"/> Notice of References Cited (PTO-892)                                            | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                        | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> | 20) <input type="checkbox"/> Other: _____                                    |

### DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All rejections and objections not repeated below are hereby withdrawn.

#### ***Claim Rejections - 35 USC § 103***

Claims 17, 2-7, 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAGLUND *et al.* (IDS reference AS) in view of HOCHMAN *et al.* (IDS reference AD).

Applicant's arguments filed 1/11/01 have been fully considered but they are not persuasive. In response to the argument that neither HAGLAND nor HOCHMAN teach or suggest a method of identifying an optical contrast agent, applicant's attention is drawn to page 313 of HAGLAND wherein HAGLAND compares behavior of different dyes in staining tumor cells, and to page 315 wherein HAGLAND teaches that dyes can be developed which target specific tumor cells. The combination of teachings by HAGLAND suggests that putative contrast-enhancing agents/dyes be compared to known dyes for use as contrast -enhancing agents in staining tumor tissue (e.g. using a known method of staining tumor tissue, as taught by HAGLAND). In response to the argument that HAGLAND and HOCHMAN teach only indocyanine green (ICG), thus motivating one skilled in the art to use only this dye as a contrast enhancing agent, applicant's attention is drawn to page 313 of HAGLAND wherein he teaches comparison of ICG to fluorescein and Evan Blue dye in staining tissue, and to col. 17,

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lines 12-18 wherein HOCHMAN teaches a variety of dyes for use in imaging tissues. HOCHMAN also teaches that dyes can be used as tissue filters and that use of a dye (contrast enhancing agent) which remains with tumor or normal tissue for a prolonged period of time is desired in his method (col. 18, lines 3-30). It would therefore have been obvious to one of ordinary skill in the art at the time of invention to have screened or tested any of the dyes taught by HAGLAND or HOCHMAN for their ability to preferentially stain or remain with a particular tissue (i.e. to have identified the dyes as contrast enhancing agents) in the method of HAGLAND and HOCHMAN where the motivation would have been to find dyes which have a high signal to noise ratio, as taught by HAGLAND (page 315) and/or which enhance sensitivity in imaging tissues, as taught by HOCHMAN (col. 18, lines 31-34). HAGLAND and HOCHMAN make obvious a method of identifying a contrast enhancing agent and teach all of the limitations recited in the instant claims, including comparison to controls, as previously set forth, therefore claims 17, 2-7, 9 and 11 are rejected.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over HAGLUND *et al.* (IDS reference AS) in view of HOCHMAN *et al.* (IDS reference AD) as applied to claim 17 above, and further in view of NEWELL *et al.* (IDS ref. CT).

Applicant claims a method of identifying optical contrast enhancing agents, as previously set forth. Claims 8 and 10 limit the sample population of the method to an in vitro culture system or to a viable sample population in a cell culture system.

HAGLUND in view of HOCHMAN make obvious a method of identifying optical contrast enhancing agents, as previously set forth and maintained above. HAGLAND and HOCHMAN do not teach an in vitro or cell culture system.

NEWELL teaches imaging of cells in culture using a computerized imaging system (p. 7705).

It would have been obvious to one of ordinary skill in the art at the time of invention to have used the cell (in vitro) culture of NEWELL as the sample population in the method of HAGLUND and HOCHMAN where the motivation would have been to facilitate use of the method by using samples of brain tissue or cells rather than intact organisms, as suggested by the cultured hippocampal tissues of NEWELL. One skilled in the art would reasonably have expected success in using cultured cells as the sample in the method of HAGLUND and HOCHMAN because all of HAGLUND, HOCHMAN, and NEWELL teach computer imaging for evaluation of stained cells/tissues. For these reasons, claims 8 and 10 are obvious.

### ***Conclusion***


Claims 2-11 and 17 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (703) 305-2363. The examiner can normally be reached on Monday to Friday, 7:30 am to 4 pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (703) 308-4028. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to a Patent Analyst, Tina Plunkett, whose telephone number is (703) 305-3524.

  
Marjorie A. Moran  
April 5, 2001

  
MARY K. ZEMAN  
PATENT EXAMINER  
AC 1631